Ontario Cancer Research Ethics Board
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Guidance

To: All Ontario Oncology Trial Centres Using OCREB

From: Ontario Cancer Research Ethics Board

Date: April 1, 2024

RE: Approval for 'administrative changes' to provincially approved participant materials/documents including the ICF - e.g., the addition of contact information, the removal of instructional text, and the approval for centre-specific changes to the ICF Compensation language

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All provincially approved OCREB study documents, including participant materials such as wallet cards and consent forms, are pre-approved for use by all participating centres with the application of 'administrative changes' to the documents. The provincially approved document version date must be maintained once the administrative changes have been applied.

This process for applying centre-specific information to the provincially approved documents without modifying the version dates and without the requirement for OCREB review is based on OCREB's policies, procedures, guidance documents, consent form templates and other applicable centre-specific documentation and on a controlled honour system between OCREB and participating sites: i.e., centres are mandated to comply with the specified implementation of the centre-specific changes, which are pre-identified and approved by OCREB as indicated in the guidance and in other centre-specific documentation. Periodic reviews or audits of centre study documents will be conducted at OCREB's discretion to demonstrate compliance with the process.

For all participating centres, the following administrative changes to the provincially approved document(s) are pre-approved for implementation:

- modification of the Compensation (reimbursement) section as follows: The statement, "You will be reimbursed for study-related expenses such as [specify, e.g., parking, etc.]", may be removed or modified, as applicable, and in accordance with local policy and/or study contract terms and as detailed in the Centre Initial Application (CIA) form and Centre Amendment submissions

- the inclusion of centre-specific information in the yellow highlighted area(s) of the provincially approved ICF, such as the designation of procedures/tests taking place at another centre. e.g., MRI; PET scans, etc.;

- the exclusion or inclusion by a centre of a clearly identified study optional component/activity in the provincially approved ICF. e.g., PK Sample collection; tissue collection which may or may not be conducted at every centre, and for which

there is instructional text to indicate that the centre should either include or remove the 'following information' as per centre requirements;

- the addition to the document(s) of centre study staff / Investigator name and contact information, centre letterhead, correction of spelling errors, the calibration of # of pages (including reference to the # of pages on the signature page for COG studies), and the removal of instructional text.

All other changes to the content of the document(s), including formatting and corrections to grammar, require a re-submission of the document and approval by OCREB.

Centres will include their most recent centre-specific pre-approved change memo with their CIA and the memo will be acknowledged in the CIA approval letter.

Note: Requests for any other centre-specific, pre-approved ICF changes must be submitted to OCREB with supporting documentation for approval prior to implementation. Contact ocrebonline@oicr.on.ca